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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/806,370
Filing Date: October 03, 2001
Appellant(s): HOLMES ET AL.

Ms. Mary E. Bak, Registration Number 31,215
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 25, 2006 appealing from the Office action mailed May 25, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect; Appellant stated at page 4 of 29, that claim 28 was indicated as allowable; claim 29 was the claim indicated as allowable. A correct statement of the status of the claims is as follows:

Claims 1-2, 13 stand rejected.

Claims 3,43 and 44 are allowed

Claims 4-11,14-17, 28-37 and 39-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 12, 18-27 and 38 have been canceled.

This appeal involves claims 1-2, and 13.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: (a) The rejection of claims 1-11,13-17,28-37 and 39-44 under the provision of 35 USC 112, second paragraph as allegedly failing to particularly point out and distinctly claim the subject matter is herein withdrawn based upon the examiner's reconsideration of the definitions in the Specification and Appellant's traversal.

Claims 1-2,4,6-8,11,13-17,28,30,32-34,37,39-43 rejected under 35 U.S.C. 102(b) as being anticipated by Rappuoli, Rino (WO95/17211) in light of evidence provided by Zhang et al (1995, page 564, Figure 1) that shows sequences for cholera toxin and E.coli heat labile enterotoxin is herein withdrawn in light of Applicant's single definition of a deleted glutamic acid only being produced by the deletion of the native position 29 of the wild type cholera toxin, which can only be produced by deletion of the amino acid at this position, as disclosed at page 4, lines 4-28 and page 8, lines 20-24, as well as Appellant's new grounds of traversal that the glutamic acid at native position 29 is not located at position 28 or 30.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 1-11,13-17,28-37 and 39-44 under the provision of 35 USC 112, second paragraph as allegedly failing to particularly point out and distinctly claim the subject matter is herein withdrawn under reconsideration of the definitions in the Specification and Appellant's traversal.

Claims 1-2,4,6-8,11,13-17,28,30,32-34,37,39-43 rejected under 35 U.S.C. 102(b) as being anticipated by Rappuoli, Rino (WO95/17211) in light of evidence provided by Zhang et al

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(1995, page 564, Figure 1) that shows sequences for cholera toxin and E.coli heat labile enterotoxin is herein withdrawn in light of Applicant's single definition of a deleted glutamic acid only being produced by the deletion of the native position 29 of the wild type cholera toxin, which can only be produced by deletion of the amino acid at this position, as disclosed at page 4, lines 4-28 and page 8, lines 20-24, as well as Appellant's new grounds of traversal that the glutamic acid at native position 29 is not located at position 28 or 30.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Glineur, C. et al "Importance of ADP-Ribosylation in the Morphological Changes of PC12 Cells Induced by Cholera Toxin" Infection and Immunity, vol. 62, no. 10 (October 1994), pp4176-4185.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Glineur, Corine et al (1994, Infection and Immunity).

Glineur et al disclose a composition comprising a mutant holotoxin with reduced toxicity (see Table 1, page 4181) cholera in combination with additional antigens, specifically a 27 and 12 kDA antigen (see page 4180, column 1, Figure 4, page 4181, lane labelled "E29Δ,"), all of the antigens produced by the recombinant host cell *Vibrio cholerae* 569B-NT upon expression, as

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well as the expressed ampicillin resistance antigen (see Figure 3, “amp”, “CTA”, “CTB” and page 4180, column 2, paragraph 1), wherein the mutant cholera holotoxin was mutated through deleting the native Glu at position 29, and replacing the deleted Glutamic acid with an amino acid that is neither glutamic acid or aspartic acid(see Figure 2, frame B, line labelled CTX A E29Δ.) , wherein the amino acid that replaced the native position 29 Glutamic acid was tyrosine.

The culture medium is a type of diluent or carrier (see page 4180, column 2, “CTX-CRM”) for the mutant cholera holotoxin/antigen composition.

The functional characteristics of the mutant holotoxin is an inherent characteristic as the mutant holotoxin of the prior art meets all of the structural characteristics and also functionally evidences reduced toxicity relative to native cholera toxin. Glineur et al inherently anticipates the claimed invention.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

(10) Response to Argument

1. Appellant asserts that the rejection of claims 1, 2, 13 under 35 U.S.C. 102(b) as being anticipated by Glineur et al (1994) is traversed on the grounds that the composition of Glineur et al is not used as an adjuvant, the adjuvant being the mutant cholera holotoxin.
2. The Examiner applied prior art consistent with Appellant’s definition and traversal directed to the mutation of a mature A subunit of a cholera holotoxin, the mutant holotoxin being defined by taking the native/wild-type amino acid sequence and determining whether the amino

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acid at the native/wild-type glutamic acid position 29 has been deleted and replaced with another amino acid other than aspartic acid. The mutant holotoxin comprising both the beta subunit, which is known to have adjuvanting activity, together with a mutant alpha subunit with reduced toxicity, the mutation being at wild-type/native position 29, wherein the native glutamic acid is replaced with tyrosine, an amino acid other than aspartic acid. The mutant holotoxin of the prior art is consistent with and encompassed by the scope Appellant's claims that replaces the native/wild-type position 29 glutamic acid with another amino acid, the mutant holotoxin of the prior art evidencing a tyrosine at native position 29.

3. Additionally, it is the position of the examiner that while the reference does not discuss the adjuvant characteristics of the mutant holotoxin composition, the mutant cholera holotoxin meets all of the required structural characteristics claimed and also evidences the functional limitation of reduced toxicity relative to the native cholera holotoxin (see Table 1, page 4181). Only composition claims have been rejected, and no methods of use have been included in the prior art rejection over Glineur et al. Glineur et al inherently anticipates the instantly claimed invention because Appellant's claimed compositions have not been distinguished from the composition of the prior art.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Ginny Allen Portner

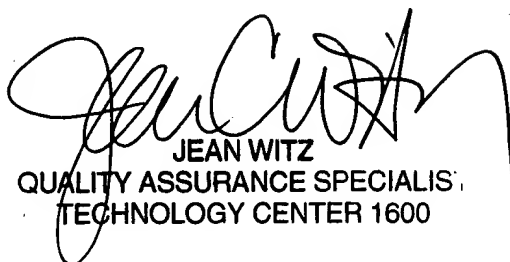


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